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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,220	07/30/2003	Fabien Marino	IPT-015.01	8295

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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,220	MARINO ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is assigned to Dr. Kailash C. Srivastava, in Art Unit 1655. To aid in correlating any papers for this application (i.e., USSN 10/630,220), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

Claims Status

2. Claims 1-63 are pending.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. §121:

- Group I – Claims 2-21 and 27-28 drawn to a method to generate cell culture comprising an organism having an exogenously regulated expression system linked to IPTG as an inducer, classified under Class 435, Subclass 170, for example
- Group II – Claims 22-23 drawn to a method to obtain a partially purified polypeptide, classified under Class 530, Subclass 333, for example.
- Group III – Claims 24-26 drawn to a method to determine the structure of a polypeptide, classified under Class 436, Subclass 173, for example.
- Group IV – Claim 29 drawn to a high-density cell culture, classified under Class 435, Subclass 71.2, for example.
- Group V – Claims 30-32 drawn to a partially purified or purified polypeptide, classified under Class 530, Subclass 810, for example
- Group VI – Claims 33-39 and 44-46 drawn to a method to contact a cell culture with a label to incorporate a label in a polypeptide during growth of high density cell culture via culturing the cell in a label incorporated culture medium to produce a labeled polypeptide from said culture cells, classified under Class 435, Subclass 968, for example.
- Group VII – Claims 40-43 drawn to a method to culture cells in a culture medium comprising metal mixture a carbon source and a source of organic nitrogen, wherein cells are cultured in

absence of an exogenously regulated expression system, classified under Class 435, Subclass 131, for example.

- Group VIII – Claims 47-50 drawn to a method to culture cells in a culture medium comprising metal mixture, a carbon source and a source of organic nitrogen, wherein cells are cultured in absence of IPTG as a inducer for the exogenously controlled expression construct system, classified under Class 435, Subclass 71.1, for example.

- Group IX– Claims 51-63 drawn to a cell culture medium comprised of a concentrated mixture comprising a variety of metals, a source of carbon and a source of organic nitrogen, and buffering salts to buffer the culture medium in pH range of 6-8, wherein the cell culture medium components are already suspended in a liquid phase or said components are in a dry solid form, wherein said dry solid phase can be hydrated with water to yield liquid culture medium, classified under Class 435, Subclass 252..1 or 253.6, for example.

Linking Claims

4. Claim 1 links inventions in Groups I-III and VI. Claim 23 links inventions in Groups II and III. Claim 1 will be examined upon election of any of the inventions in Groups I-III and VI. Likewise, Claim 23 will be examined upon election of any of the Groups II-III. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claims, identified above. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. §121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131- 32 (CCPA 1971). See also MPEP §804.01.

Inventions are Independent or Distinct

5. The inventions are independent or distinct, each from the other because of the following reasons:

Inventions in Groups I-III and VI-VIII are unrelated to each other because each one of them is

directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claim encompassed in Group I is directed to a method to culture high density culture of a bacterium with an externally controlled expression system, wherein said expression system is controlled with an inducer. Inventions in Groups III or VIII, on the other hand do not require IPTG as an inducer of externally controlled expression system. Therefore, the methods claimed in inventions I-III, or VI-VIII will not be practiced together.

Invention in Group IV is related to inventions in Groups I and VI-VIII as product and process to make the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, for e.g., the method of Claim I to prepare high density cell culture of Group IV is also applicable to make a variety of products via high density cell cultivations, (e.g., beer making). Similarly, said high-density cell culture may also be prepared by solid-state fermentation (e.g., koji fermentation).

Inventions in Groups IV and V are unrelated to each other because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claim encompassed in Group IV is directed to a high-density culture of a bacterium, wherein said bacterium produces a polypeptide. Invention in Group V, on the other hand drawn to a purified or partially purified polypeptide. Thus, the two compositions are products-by-process, i.e., regardless of the manner in which the polypeptide is produced; the cell density will not change the polypeptide composition or properties.

Inventions in Groups IV-V are related to invention in Group IX as sub-combinations disclosed as usable together in a single combination. The sub-combinations are distinct from each other if they are shown to be separately usable. In the instant case for example, invention in Group X has separate utility because the culture medium of Group IX is applicable for preparing any microbial cells to produce materials (e.g., lactic or citric acid) other than a polypeptide. See MPEP § 806.05(d). Likewise, the

polypeptides encompassed in the invention of Groups IV-V may also be produced via a non-fermentative process that does not require a culture medium of Group IX composition.

The invention in Group V is related to inventions in Groups I-III and VI-VIII as product and process to make the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method to prepare partially purified or purified peptide is also applicable to make any purified fermentation product (e.g., citric acid) via high-density cell cultivations in a cell culture medium. Similarly, said partially purified peptide or polypeptide can also be prepared via enzymatic digestion of a protein followed by chromatography, x-ray crystallography/ mass spectrometry or other instrumentation methods (e.g., preparative high pressure liquid chromatography followed by x-ray diffraction).

Invention in Group IX is related to inventions in Groups I-II and VI-VIII as product and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. The process of making a high density cell culture can also be attained with a culture medium comprising grains and molasses or just flours (e.g., koji preparation). Similarly, the culture medium of Group IX is also applicable to prepare a variety of fermentation products (e.g., fatty acids, alcohol, proteins, restriction endonucleases, components for pharmaceuticals etc.)

The inventions in Groups II-III are unrelated to invention in Group IV and invention in Group III is unrelated to invention in Group IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04 and MPEP §808.01). In the instant case the methods of Groups II-III are not applicable to prepare product of Group IV. Also, the method of Group III is not applicable for the preparation of the product in Group IV from the composition in Group IX invention.

The inventions discussed above are independent or distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive, particularly with regard to the literature search because each of the groups would require a search strategy different from the one required for the other. For e.g., invention in group III is specific to a method to purify polypeptides and would, therefore, require a different set of key words featuring the purification alternatives for said product in contrast to those required to search the invention in Group I encompassing method to culture

a cell, or the composition of Group IX drawn specifically to cell culture media. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. For, e.g., invention in Group I is drawn to a method to make a product, invention in Group V to a product (i.e., purified polypeptide) that is not obtained according to the method of Group I and the composition in Group IX that is not required to practice the method of Group III. Thus, it would be an undue burden to examine all of the above inventions in one application. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (Class and subclass), and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

6. Applicants are advised that a reply to this requirement must include an identification of an invention elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of additional claims which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b). Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed

product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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Art Unit 1655
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March 20, 2006

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER